

Protalix BioTherapeutics, Inc.
Form 8-K
September 08, 2009

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): September 8, 2009

Protalix BioTherapeutics, Inc.
(Exact name of registrant as specified in its charter)

Florida
**(State or other jurisdiction
of incorporation)**

000-33357
(Commission File Number)

65-0643773
**(IRS Employer
Identification No.)**

2 Snunit Street
Science Park, POB 455
Carmiel, Israel
**(Address of principal executive
offices)**

20100
(Zip Code)

Registrant's telephone number, including area code +972-4-988-9488
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events

On September 8, 2009, Protalix BioTherapeutics, Inc. (the Company) issued a press release announcing that it has received notice from the U.S. Food and Drug Administration (FDA) that the FDA's Office of Orphan Products Development has granted orphan drug designation to prGCD, the Company's proprietary plant cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of Gaucher disease. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated September 8, 2009.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROTALIX BIOTHERAPEUTICS, INC.

Date: September 8, 2009

By: /s/ David Aviezer
Name: David Aviezer,
Ph.D. Title: President and Chief
Executive Officer

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